

Subject: Pre-Transplant Evaluation		Original Effective Date: 9/13/18
Policy Number: MCP-323	Revision Date(s):	
Review Date:		
MCPC Approval Date: 9/13/18		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

RECOMMENDATION

All pretransplant evaluations require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Medical Director or qualified clinical designee. All other transplants will be by the Corporate Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, state regulations and/or MCP policies the Corporate Medical Director's designee can approve the requested transplant.

Members must meet UNOS/OPTN policies and guidelines for pretransplantation evaluation and listing criteria and the diagnosis must be made by a *Specialist in the Disease* and or Transplant Surgeon.

Pre-Transplant Evaluation:

Criteria for transplant evaluation include all of the following: [ALL]

- History and physical examination: includes a complete evaluation that meets the transplant center's protocol eligibility criteria
- Psychosocial evaluation and clearance:
 - No behavioral health disorder by history or psychosocial issues:
 - if history of behavioral health disorder, no severe psychosis or personality disorder
 - mood/anxiety disorder must be excluded or treated

- member has understanding of surgical risk and post procedure compliance and follow-up required
 - Adequate family and social support
- EKG
- Chest x-ray
- Cardiac clearance in the presence of any of the following:
 - chronic smokers
 - > 50 years age
 - those with a clinical or family history of heart disease or diabetes
- Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease
- Lab studies:
 - *Complete blood count, Kidney profile (blood urea nitrogen, creatinine), electrolytes, calcium, phosphorous, albumin, liver function tests, Coagulation profile (prothrombin time, and partial thromboplastin time)
 - *Serologic screening for HIV, Epstein Barr virus (EBV), Hepatitis virus B (HBV), and Hepatitis C(HCV), cytomegalovirus (CMV), RPR and/or FTA:
 - If HIV positive all of the following are met:
 - CD4 count >200 cells/mm-3 for >6 months
 - HIV-1 RNA undetectable
 - On stable anti-retroviral therapy >3 months
 - No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm)
 - If abnormal serology need physician plan to address and/or treatment as indicated
 - UDS (urine drug screen) if patient is current or gives a history of past drug abuse
- *Colonoscopy (if indicated or if patient is 50 ≥ older should have had an initial screening colonoscopy, after initial negative screening requires follow up colonoscopy every ten years) with complete workup and treatment of abnormal results as indicated
- *GYN examination with Pap smear for women ≥ 21 to ≤ 65 years of age or indicated (not indicated in women who have had a TAH or TVH) with in the last three year with complete workup and treatment of abnormal results as indicated

Within the last 12 months:

- Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre or post-transplant
- *Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated
- *PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated

***Participating Centers of Excellence may waive these criteria**

The requesting transplant recipient should not have any of the following **absolute contraindications**:

- Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery

- Malignant neoplasm with a high risk for recurrence, non-curable malignancy (excluding localized skin cancer)
- Systemic and/or uncontrolled infection
- AIDS (CD4 count < 200cells/mm³)
- Unwilling or unable to follow post-transplant regimen
 - Documented history of non-compliance
 - Inability to follow through with medication adherence or office follow-up
- Chronic illness not irreversible with transplant with one year or less life expectancy
- Limited, irreversible rehabilitation potential
- Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present
- No adequate social/family support

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	Any/All

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

RESOURCE REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services. NCD for Stem Cell Transplantation & NCD for multiple NCD for solid organ transplant. Accessed at: <http://www.cms.gov/medicare-coverage-database/>

Professional Society Guidelines

2. National Marrow Donor Program[®] (NMDP) and the American Society for Blood and Marrow Transplantation (ASBMT) referral guidelines: Recommended Timing for Transplant Consultation. Accessed at: <https://bethematchclinical.org/Transplant-Indications-and-Outcomes/Referral-Timing-Guidelines/>
3. National Marrow Donor Program[®] (NMDP). Patient Eligibility for HCT. Accessed at: <https://bethematchclinical.org/Transplant-Indications-and-Outcomes/Eligibility/>
4. Organ Procurement Transplant Network OPTN and United Network for Organ Sharing (UNOS):
 - OPTN/UNOS Policies accessed at: <http://optn.transplant.hrsa.gov/>
 - UNOS Policy accessed at: https://unos.org/policy/?gclid=EAIaIQobChMIj5yBk9vx2wIVBdRkCh2Whw3uEAAYASAAEgILZfD_BwE
5. Steinman TI, Becker BN, et al.; Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation.
6. AST Infectious Disease Community of Practice. Pre-Transplant Evaluation & Vaccinations in Solid Organ Transplant Recipients. Accessed at:

Other Resources

7. McKesson InterQual Criteria for Procedures: InterQual Transplantation Criteria. [Multiple subsets]. 2018.
8. Milliman MCG Criteria for Transplantation. [Multiple subsets]. 2018.
9. UpToDate: [Website] Waltham, MA: Walters Kluwer Health; 2018
 - Holmberg L, Deeg H, Sandmaier B. Determining eligibility for autologous hematopoietic cell transplantation.
 - Deeg HJ, Sandmaier B. Determining eligibility for allogeneic hematopoietic cell transplantation
 - Fishman J. Evaluation for infection before solid organ transplantation.
 - Wingard J. Evaluation for infection before hematopoietic cell transplantation.
 - Rossi AP. Evaluation of the potential renal transplant recipient.
 - Dove LM, Brown RS. Liver transplantation in adults: Patient selection and pretransplantation evaluation.
 - Mancini D. Indications and contraindications for cardiac transplantation in adults.
 - Hachem RR. Lung transplantation: General guidelines for recipient selection.
 - Klein CL, Alhamad T. Patient selection for and immunologic issues relating to kidney-pancreas transplantation in diabetes mellitus.
10. Advanced Medical Review (AMR): Policy reviewed by practicing MD board certified in Surgery General, Surgery Transplant. 6/28/18

Review/Revision History:

2018: Policy created.